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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,494	08/28/2003	Bradley T. Estes	MSDI-479/PC-457.06	6987
52196 7590 12/09/2008 KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER SWIGER III, JAMES L	
			ART UNIT 3775	PAPER NUMBER
			MAIL DATE 12/09/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/650,494

Applicant(s)

ESTES ET AL.

Examiner

JAMES L. SWIGER III

Art Unit

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2.3.15.28-36.38-44.46-61.63-72 and 77-88 is/are pending in the application.
- 4a) Of the above claim(s) 4.32-34.47-49.51-56.65.66.77 and 78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2.3.15.28-31.35.36.38-44.46.50.57-61.63.64.67-72 and 79-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/28/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/2007 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2-3, 15, 28-31, 35, 38, 46, and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Shikinami (US Patent Number 6,281,262), previously cited by applicant.

Shikinami discloses various embodiments of an expandable spacers (see figures 24, 25) for implantation between opposing endplates of adjacent vertebrae, the spacer comprising an elongate, cylindrical body composed of a shape memory polymeric material and comprising a first bearing surface and an opposite second bearing surface and a peripheral sidewall positioned therebetween and defining an interior cavity,

wherein the peripheral wall comprises at least one opening extending into the interior cavity, the body can be provided in a first configuration wherein the body expands to a second configuration, the second portion having a greater area than the first portion, wherein the first configuration has a first width and the second configuration has a second width, wherein the second width can be greater than the first width, wherein the shape memory polymeric material is selected from the group consisting of polylactide, polyglycolide, poly(lactide-co-glycolide), polyurethane, poly(ethylene-co-vinyl acetate), poly(ethylene-co-propylene), poly(ethylene-co-propylene-co-dien-e), poly(ξ -caprolactone), poly(β -hydroxybutyrate), poly(β -hydroxybutyrate-co-hydroxyvalerate), poly(methacrylate), poly(methylmethacrylate), poly(acrylate), and mixtures, copolymers and blends thereof (see column 2, lines 28-31), wherein the peripheral wall can contact the apophyseal ring of the vertebral endplate. The body in the first configuration is compressed into a flattened configuration (see various embodiments disclosed in figures 1-28).

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Shikinami, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not

differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shikinami (US Patent Number 6,281,262) in view of Stubstad et al. (US Patent 3,867,728). Shikinami discloses the claimed invention except for a peripheral sidewall that has two thicknesses in a cross sectional area. Stubstad discloses a spacer that has sidewalls (44) having two dimensions (see Figs. 8-9). Having sidewalls with varying thicknesses help to assist the spacer in maintaining the intervertebral space with respect to varying compressive loads. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Shikinami (US Patent Number 6,281,262) having the varying wall thickness of Stubstad '728 so that the compressive forces of the intervertebral areas may be fully supported.

Claims 36 and 80-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shikinami (US Patent Number 6,281,262), previously cited by applicant.

Shikinami discloses the claimed invention except the use of two spacers. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the assembly of Shikinami with two spacers, since it has been held

that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Furthermore, see evidentiary patent to Ferree (US Patent Number 6,491,724), previously cited by examiner. In addition, the first and the second expandable spacers can be composed of the same shape memory polymeric material, wherein the second expandable spacer is provided in a third configuration and sized substantially the same as the first spacer in the first configuration, wherein the second spacer expands to a fourth configuration and is sized substantially the same as the first spacer in the second configuration, wherein the second spacer expands to a fourth configuration and is sized differently than the first spacer in the second configuration, wherein the second expandable spacer is provided in third configuration and is sized differently than the first spacer in the first configuration. wherein the second spacer expands to a fourth configuration and is sized substantially the same as the first spacer in the second configuration, wherein the second spacer expands to a fourth configuration and is sized differently than the first spacer in the second configuration, wherein the first spacer is a mirror image of the second spacer (see various embodiments disclosed in figures 1-28).

Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shikinami (US Patent Number 6,281,262), in view of Ferree (US Patent Number 6,491,724).

Shikinami discloses the claimed invention except for the use of osteogenic material in the internal cavity, wherein the osteogenic material is selected from the group consisting of: a bone morphogenic protein, a recombinant bone morphogenic

protein, demineralized bone matrix, and mixtures thereof. Ferree discloses an expandable spacer and teaches the use of osteogenic material in the internal cavity and teach the use of osteogenic material to promote bone ingrowth (see column 2, lines 2-7). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Shikinami using osteogenic material in the internal cavity, wherein the osteogenic material is selected from the group consisting of: a bone morphogenic protein, a recombinant bone morphogenic protein, demineralized bone matrix, and mixtures thereof, in view of Ferree, to promote bone ingrowth.

Claims 59-64, 67, 70, 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Shikinami and Stubstad as applied to claim 42 above and in view of Ferree (US Patent Number 6,491,724).

The combination of Shikinami and Stubstad disclose the claimed invention except for the use of osteogenic material in the internal cavity, wherein the osteogenic material is selected from the group consisting of: a bone morphogenic protein, a recombinant bone morphogenic protein, demineralized bone matrix, and mixtures thereof. Ferree discloses an expandable spacer and teaches the use of osteogenic material in the internal cavity and teach the use of osteogenic material to promote bone ingrowth (see column 2, lines 2-7). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of the combination of Shikinami and Stubstad using osteogenic material in the internal cavity, wherein the osteogenic material is selected from the group consisting of: a bone morphogenic protein, a

recombinant bone morphogenic protein, demineralized bone matrix, and mixtures thereof, in view of Ferree, to promote bone ingrowth.

Regarding claims 68, 69, 71, and 72, the combination of Shikinami and Stubstad and Ferree disclose the claimed invention except the body exhibiting a compressive modulus of between about 2 MPa and about 30 MPa or between about 8 MPa and about 15 MPa, and a height between about 3 and about 20 mm or between about 4 and about 14 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Shikinami and Stubstad and Ferree with the body exhibiting a compressive modulus of between about 2 MPa and about 30 MPa or between about 8 MPa and about 15 MPa, and a height between about 3 and about 20 mm or between about 4 and about 14 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shikinami (US Patent Number 6,281,262).

Shikinami discloses the claimed invention except the body exhibiting a compressive modulus of between about 2 MPa and about 30 MPa or between about 8 MPa and about 15 MPa, It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Shikinami with the body exhibiting a compressive modulus of between about 2 MPa and about 30 MPa or between about 8 MPa and about 15 MPa, since it has been held that where the general

conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments with respect to claims 2-3, 15, 28-31, 35-36, 38-44, 46, 50, 57-61, 63-64, 67-72, 79-88 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER III whose telephone number is (571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/
Examiner, Art Unit 3775
/Eduardo C. Robert/
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